

SOUTHERN HEALTH AUDITING TOOL - SHORT AUDIT (September 2008)

Project title:

HREC Reference No.:

Principal Investigator:

Study Co-ordinator:

	Issue		Finding	Comments	Action	Complete
Prior to audit - Ethics Office background information						
1.	Project summary:					
1.1	Approval date					
1.2	Most recent Annual report					
1.3	Number of participants recruited as per Annual report					
1.4	Southern Health HREC approved sites					
1.5	Principal Investigator					
1.6	Associate Researchers					
1.7	Contact person					
1.8	Department					
1.9	No. of amendments approved					
1.10	Amendments pending	Yes / No				
1.11	Most recently approved protocol version & date					
1.12	Most recently approved PICF version & date					
1.13	Expected completion date					
1.14	Expected number of participants					
Audit - interview with researcher / coordinator						
2.	General details:					
2.1	Study sites as per approval	Yes / No / NA				
2.2	Change in researchers not yet approved by Ethics Committee	Yes / No / NA				
2.3	Expected completion, explanation of delay if applicable					
2.4	Registered with clinical trials register fulfilling ICMJE criteria, if applicable	Yes / No / NA				
2.5	Sponsor name					
2.6	Sponsor monitoring / audit, frequency					
2.7	Publication of any results/findings	Yes / No / NA				
3.	Protocol:					
3.1	Version and date of approval					
3.2	Amendments and approval certificates sighted	Yes / No / NA				
3.3	Interventions as per protocol	Yes / No / NA				
3.4	Approved questionnaires / interview schedules used	Yes / No / NA				
3.5	any new safety information reported	Yes / No / NA				

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4.	Recruitment:					
4.1	Does this project involve recruitment of participants	Yes / No				
4.2	Numbers recruited so far					
4.3	Changes notified to the HREC, check amendments	Yes / No / NA				
4.4	All documents used in recruiting participants have been approved	Yes / No / NA				
5.	Participant information, consent and withdrawal:					
5.1	PICF version being used, same as most recently approved	Yes / No / NA				
5.2	Consent forms signed and dated by participants	Yes / No / NA				
5.3	Copy / original given to participant	Yes / No / NA				
5.4	Copy in medical record / study listed on alert sheet	Yes / No / NA				
5.5	No. of withdrawals, reasons					
6.	Privacy and confidentiality:					
6.1	Hard copies of data containing identifying information stored securely to maintain confidentiality of participants	Yes / No / NA				
6.2	Electronic files with identifying information stored securely to maintains confidentiality of participants	Yes / No / NA				
6.3	Biological samples / specimens stored securely to maintains confidentiality of participants	Yes / No / NA				
6.4	Who has access to study data, identifiable, re-identifiable					
7.	Serious Adverse Events (SAEs):					
7.1	Is there a Monitoring body such as a Data Safety Monitoring Board (DSMB) (if yes ask to see reports)	Yes / No / NA				
7.2	Have Local SAEs occurred and been reported	Yes / No / NA				
7.3	Have SAEs been reported to:					
7.3.1	- Medical personnel	Yes / No / NA				
7.3.2	- Southern Health HREC	Yes / No / NA				
7.3.3	- Insurance authority	Yes / No / NA				
7.3.4	- Sponsor	Yes / No / NA				
7.4	Should any hospital practices be changed as a result of this study?	Yes / No / NA				
8.	Study management:					
8.1	All approval certificates sighted	Yes / No / NA				
8.2	Annual Reports sighted	Yes / No / NA				
8.3	Research activity as per schedule	Yes / No / NA				
8.4	Safety arrangements for study staff adequate	Yes / No / NA				
8.5	Adequate training of staff as per protocol	Yes / No / NA				
8.6	Self-audit tool	Yes / No / NA				

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9.	Insurance / Compensation:					
9.1	Insurance Certificate current	Yes / No / NA				
9.2	Compensation payouts	Yes / No / NA				
10.	Data Management:					
10.1	Backup procedures adhered to	Yes / No / NA				
11.	Data Integrity (source data verification):					
11.1	Research data secured safely as per HREC application approved	Yes / No / NA				
12.	Databank storage for future use					
12.1	Is the data/tissue being stored securely?	Yes / No / NA				
12.2	Are there restrictions on access only to researchers/custodians associated with the research project?	Yes / No / NA				
12.3	Is confidentiality being maintained & every precaution being taken to prevent data/tissue being used or becoming available for use to which participants did not consent?	Yes / No / NA				
13.	SOP compliance					
13.1	Study site master file sighted (SOP2)	Yes / No / NA				
13.2	PICF forms sighted (SOP6)	Yes / No / NA				
13.3	Investigational Site Qualifications, Adequacy of Resources and Training Records up-to-date (SOP1)	Yes / No / NA				
13.4	case report forms, source document , record keeping and archiving sighted (SOP7)	Yes / No / NA				
13.5	Correct Handling & Shipping of infectious substances (SOP12)	Yes / No / NA				
14.	Other issues:					
14.1	Interim results available	Yes / No				
14.2	Are there any concerns you have about the study?	Yes / No				
14.3	Are there any Ethics Committee compliance issues that you need assistance with?	Yes / No				
14.4	Are you aware of:					
14.4.1	- our website	Yes / No				
14.4.2	- Southern Health HREC policies	Yes / No				
14.4.3	- National Statement 2007	Yes / No				
14.4.4	- Australian Code (2007)	Yes / No				
14.4.5	- VMIA guidelines	Yes / No				
14.4.6	- ACHS research standards	Yes / No				

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<i>Post Audit - Ethics Office follow up</i>						
15.	Correspondence and actions:					
15.1	Issues of concern	Yes / No				
15.2	Letter sent requesting response to requested actions	Yes / No				
15.3	Response received	Yes / No				
15.4	Further action required	Yes / No				
15.5	Project status					
15.6	Final thank you letter sent	Yes / No				